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10/613,842	07/03/2003	Daryl E. Anderson	200208831-1	6766
22879 7590 05/11/2010 HEWLETT-PACKARD COMPANY Intellectual Property Administration 3404 E. Harmony Road Mail Stop 35 FORT COLLINS, CO 80528			EXAMINER SU, SUSAN SHAN	
			ART UNIT 3761	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary**Application No.**

10/613,842

Applicant(s)

ANDERSON ET AL.

Examiner

SUSAN SU

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20, 22-29, 31-33 and 35-42 is/are pending in the application.
- 4a) Of the above claim(s) 33 & 35-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20, 22-29, 31 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2 April 2010 has been entered.

Status of Claims

Claims 1-20, 22-29, 31-33, and 35-42 are pending, of which Claims 1-4, 28, 31, and 33 are amended and Claims 33 and 35-42 are withdrawn. Claims 1-20, 22-29, 31, & 32 are examined on the merits. No new matter is added.

Response to Arguments

2. Applicant's arguments filed 2 April 2010 have been fully considered but they are not persuasive. Applicant first argues that primary reference Beverly teaches an ophthalmic device that provides feedback to the operator rather than the subject who is receiving the dispensed fluid. However, it is noted that in independent claims 20 & 28, the limitation is part of the intended use language. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Furthermore, the feedback provided by Beverly to the operator, who

can either move the apparatus or tell the subject to move the eye, thus results in the eye of the subject being moved "relative to the dispensing apparatus."

35 USC § 112, 6th Paragraph

3. With regard to Applicant's "detecting means for detecting...; feedback means for receiving information...; and dispensing means for dispensing..." and "means for capturing an image...; processing means for detecting the position of the eye..." of claims 28 & 29, the language appears to be an attempt to invoke 35 USC 112, 6th paragraph interpretation of the claims. A claim limitation will be interpreted to invoke 35 USC 112, 6th paragraph if it meets the following 3-prong analysis:

- (A) the claim limitations must use the phrase "means for" or "step for;"
- (B) the "means for" or "step for" must be modified by functional language; and
- (C) the phrase "means for" or "step for" must not be modified by sufficient structure, material or acts for achieving the specified function.

If the examiner finds that a prior art element:

- (A) performs the function specified in the claim,
- (B) is not excluded by any explicit definition provided in the specification for an equivalent, and
- (C) is an equivalent of the means- (or step-) plus-function limitation,

then the prior art element may be considered by the examiner to be an equivalent to the means plus function limitation, and the prior art may anticipate the claimed limitation.
See MPEP 2183.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 28, 29, 31, & 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It appears that that the claim elements "detecting means for detecting...; feedback means for receiving information...; and dispensing means for dispensing..." and "processing means for detecting the position of the eye..." are means (or step) plus function limitations that invokes 35 U.S.C. 112, sixth paragraph. However, it is unclear whether the claim element is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph, because each of the "means for" has been modified by sufficient structure or acts (e.g. "detecting," "feedback," "dispensing," and "processing"). If applicant wishes to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant is required to:

- (a) Amend the claim to include the phrase "means for" or "step for" in accordance with these guidelines: the phrase "means for" or "step for" must be modified by functional language and the phrase must **not** be modified by sufficient structure, material, or acts for performing the claimed function; or
- (b) Show that the claim limitation is written as a function to be performed and the claim does **not** recite sufficient structure, material, or acts for performing the claimed function which would preclude application of 35 U.S.C. 112, sixth paragraph. For more information, see MPEP § 2181.

The claim terms are thus given their broadest reasonable interpretation because the third requirement for invoking 35 U.S.C. 112, 6th paragraph has not been met.

Specification

6. The disclosure is objected to because of the following informalities:

In Claim 29 specifically, claim element "means for capturing an image of the eye" is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. The written description only implicitly or inherently sets forth the corresponding structure, material, or acts that perform the claimed function.

Pursuant to 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181, applicant is required to:

- (a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or
- (b) Amend the written description of the specification such that it **expressly recites** the corresponding structure, material, or acts that perform the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or
- (c) **State on the record** what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function.

In the instant case, Examiner considers any camera to be an equivalent to the "means for capturing an image of the eye" disclosed by applicant, since it performs the same function of capturing/obtaining an image of the eye in the same way as the claimed function, with the same result as the device disclosed by Applicant. Additionally, the camera is the structural equivalent of the claimed means for capturing an image of the eye. See MPEP 2183.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 2, 4, 9, & 16 are rejected under 35 U.S.C. 102(a) or (e) as being anticipated by Kerssies (US 2004/0267214).

With regard to Claim 1, Kerssies teaches an ophthalmic apparatus comprising:

an eye-positioning device (3) comprising:

a feedback device (the reflective material on the inside of device 3 provides feedback to the user, [0013]) configured to provide information to a subject who is moving an eye from a current position to a desired position relative to the eye positioning device; and

an applicator (5) for dispensing the fluid into the eye.

The language "conditionally upon positioning of the eye in the desired position" is deemed to be functional language. The applicator of Kerssies is capable of being squeezed and thus allows for dispensing of fluid when the user chooses to do so. When the user sees in the reflection that his/her eye is in the correct position, s/he would be able to decide whether or not to dispense fluid into the eye.

With regard to Claim 2, Kerssies also teaches an eye-position detector (interior of device 3) for detecting the position of the eye.

With regard to Claim 4, Kerssies also teaches that the feedback mechanism is operable to provide visual cues (a reflection is a visual cue) that assist the subject in moving the eye to the desired position.

With regard to Claim 9, Kerssies also teaches that the applicator comprises:

a frame for wearing on the head of the subject;

a fluid dispenser (e.g. nozzle of 5) supported by the frame proximate the eye of the subject, the fluid dispenser configured to dispense fluid into the eye.

With regard to Claim 16, Kerssies also teaches that the applicator further comprises a fluid reservoir (5) for storing the fluid and delivering the fluid to the fluid dispenser.

9. Claims 20 & 23 are rejected under 35 U.S.C. 102(a) or (e) as being anticipated by Beverly (US 6,945,650).

With regard to Claim 20, Beverly teaches an ophthalmic apparatus, comprising:

a dispensing apparatus/means (12) for dispensing fluid into an eye of a subject only when the eye is in a predetermined position;

an eye-position detector/detecting means (42A & 42B) for detecting the current position of the eye relative to the dispensing apparatus; and

a feedback device/means (24) for receiving information from the detecting means corresponding to the position of the eye.

The claim language "for providing feedback information that assists the subject in moving the eye from the current position to a predetermined position relative to the ophthalmic/dispensing apparatus" is drawn to intended use of the feedback

device/means. While features of an apparatus may be recited either structurally or functionally, claims directed to a device must be distinguished from the prior art in terms of structure rather than function, because device claims cover what a device is, not what a device does (*Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990)). Thus, if a prior art structure is capable of performing the intended use as recited in a claim, then it meets the claim. Beverly's device is capable of providing information that helps the subject in moving the eye.

With regard to Claim 23, Beverly also teaches a processor (60) and an image pick-up device (inherent since an image of the eye is provided on display 24) for capturing an image of the eye. The claim language "for processing the image of the eye and determining whether the eye is in the desired position for administering the fluid to the eye" is considered to be intended use of the processor. Since the prior art invention substantially meets the structure of the current device as claimed, it is capable of performing the intended use and therefore meets the claim.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1, 2, 4-6, 8-9, 16, 28, 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beverly in view of Kerssies.

With regard to Claims 1 & 2, Beverly teaches an ophthalmic apparatus comprising:

an eye-positioning device comprising:

a feedback device (24) configured to provide information for the eye of a subject to be aligned with a desired position on the eye positioning device; and

an applicator (12) for dispensing fluid into the eye conditionally upon positioning of the eye in the desired position;
an eye-position detector (42A & 42B) for detecting the position of the eye.

Beverly does not teach that the feedback device is *configured* to provide information to a *subject*. Kerssies teaches an ophthalmic device that provides feedback to the subject so that the subject can choose to move the eye to a desired position so that eye drops will be dispensed onto the iris.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Beverly with the teaching of Kerssies to provide feedback directly to the subject for the purpose of allowing the ophthalmic device to be used in the absence of a separate operator.

With regard to Claim 4, Beverly also teaches that the feedback device provides visual cues (Col. 8 lines 35-37).

With regard to Claim 5, Beverly also teaches a display (24) for displaying a real-time image of the eye and a target (as outlined by polar array 82), such that when the eye is aligned with the target, the eye is in the desired position.

With regard to Claim 6, Beverly also teaches a processor (60) and an image pick-up device (inherent since an image of the eye is provided on display 24) for capturing an image of the eye. The claim language "for processing the image of the eye and determining whether the eye is in the desired position for administering the fluid to the eye" is considered to be intended use of the processor. Since the prior art invention

substantially meets the structure of the current device as claimed, it is capable of performing the intended use and therefore meets the claim.

With regard to Claim 28, Beverly teaches an ophthalmic apparatus, comprising:

- a detecting means (42A & 42B) for detecting the position of the eye;
- a feedback device/means (24) for receiving information from the detecting means corresponding to the position of the eye; and
- a dispensing means (12) for dispensing fluid into an eye of a subject only when the eye is in a predetermined position;

Beverly does not teach dispensing a *liquid*. Kerssies teaches an ophthalmic device that helps the subject position his/her eye for dispensing of a liquid eye drop.

The claim language "for providing feedback information that assists the subject in moving the eye from the current position to a predetermined position relative to the ophthalmic/dispensing apparatus" is drawn to intended use of the feedback device/means. While features of an apparatus may be recited either structurally or functionally, claims directed to a device must be distinguished from the prior art in terms of structure rather than function, because device claims cover what a device is, not what a device does (*Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990)). Thus, if a prior art structure is capable of performing the intended use as recited in a claim, then it meets the claim. Beverly's device is capable of providing information that helps the subject in moving the eye. Furthermore, Kerssies also teaches providing feedback information to the subject so that the eye drops may be dispensed accurately into the eye of the subject.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Beverly with Kerssies for the purpose of obviating the need of an operator and to adapt the device for use with therapeutic eye drops.

With regard to Claims 8 & 31, Beverly also teaches feedback signals (such as polar array 82 and LED array 90 presented on display 24 that indicate if the pupil/iris is positioned correctly), the feedback signals corresponding to directions for moving the eye to the desired position. The limitation regarding the signals being provided to *the subject* is already taught by Kerssies as explained above.

With regard to Claims 9 & 16, Beverly does not teach that the applicator comprises a frame or spectacle for wearing on the head of the subject and a fluid dispenser supported by the frame. Kerssies teaches an ophthalmic device with a frame (3) for wearing on the head, a fluid dispenser (nozzle of 5) supported by the frame, and a fluid reservoir (5) for storing fluid and delivering the fluid to the fluid dispenser. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Beverly with the teachings of Kerssies so that the ophthalmic device/apparatus may be more portable.

14. Claims 3 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beverly and Kerssies as applied to Claim 1 or 2 above, and further in view of Yee (US 6,270,467). Beverly and Kerssies do not teach an audible cue. Yee teaches an ophthalmic apparatus providing audible cues (30). Yee also teaches a user interface (5, 68) that can be programmed to set the operating parameters of the apparatus and a graphical interface element (6, 70). It would have been obvious to one of ordinary skill

in the art at the time of the invention to modify Beverly and Kerssies with Yee for the purpose of lending a user assistance to align his/her eyes for the subsequent medical procedure and for making the device more user-friendly.

15. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beverly and Kerssies in view of Miwa (US 6,299,305). Beverly and Kerssies do not expressly teach a CCD camera. Miwa teaches an ophthalmic apparatus that uses a CCD camera (10). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Beverly and Kerssies with Miwa for the purpose of using a standard technology for capturing the position of the eye.

16. Claims 10 & 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beverly and Kerssies in view of Vo (US 5,171,306).

With regard to Claims 10 & 14-15, Beverly and Kerssies do not teach that the frame comprises a spectacle frame or a controller for actuating the fluid dispenser to dispense a predetermined dosage. Vo teaches a spectacle-style applicator with a fluid dispenser (400 & 500) supported by the frame and a controller (Col. 9 lines 15-16) that actuates the fluid dispenser to dispense a predetermined dosage of fluid (Col. 4 lines 29-30). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Beverly and Kerssies with Vo for the purpose of adapting the alignment apparatus for more comfortable wear and for having better control over the amount of fluid dispensed into the eye.

17. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beverly, Kerssies, and Vo as applied to Claim 9 above, and further in view of Bertera

(US 5,368,582). Beverly, Kerssies, and Vo do not teach a jet dispenser. Bertera teaches a spectacle-like device with a thermal or piezoelectric jet dispenser (14) with a plurality of orifices to apply treating fluid into an eye (Col. 5 lines 1-12, Col. 9 lines 3-17, Fig. 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Beverly, Kerssies, and Vo for the purpose of utilizing a known and practiced technology for dispensing a dosage of treating fluid to the eye.

18. Claims 17 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beverley and Kerssies as applied to Claims 1 or 28 above, and further in view of Bertera (US 5,368,582). Beverly and Kerssies do not teach a jet dispenser. Bertera teaches a spectacle-like device with a thermal or piezoelectric jet dispenser (14) with a plurality of orifices to apply treating fluid into an eye (Col. 5 lines 1-12, Col. 9 lines 3-17, Fig. 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Beverly and Kerssies for the purpose of utilizing a known and practiced technology for dispensing a dosage of treating fluid to the eye.

19. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beverley in view of Vo. Beverly does not teach a spectacle frame. Vo teaches a spectacle-style applicator with a fluid dispenser (400 & 500) supported by the frame. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Beverly with Vo for the purpose of adapting the alignment apparatus of Beverly to be more portable and for more comfortable wear.

20. Claims 24-25 & 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beverly as applied to Claim 23 above, and further in view of Wickham et al. (US

6,159,186, "Wickham"). Beverly does not teach that the image capture device is a digital camera. Wickham teaches a fluid delivery system that employs a digital camera (28) as an image uptake device, and an image processor (34) capable of processing that camera's images (Col. 2 line 66 to Col. 3 line 13). Beverly's processor is also capable of detecting the position of the eye relative to the predetermined position based on the information from the eye-detectors. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Beverly with Wickham for the purpose of utilizing a known technology to better determine the eye position.

21. Claims 26 & 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beverly and Wickham as applied to Claim 25 above, and further in view of Vo. Beverly and Wickham do not teach a controller for controlling the fluid dispenser. Vo teaches a controller (Col. 9 lines 15-16) that controls a fluid dispenser. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Beverly with Wickham and Vo for the purpose of utilizing a known technology to better determine the eye position and to have better control over how and when the fluid is dispensed. It would also be obvious to combine the processor of Wickham and the controller of Vo into one single processing unit for the purpose of making it possible to make the processing unit more compact.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN SU whose telephone number is (571)270-3848. The examiner can normally be reached on M-F 9:00AM-5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Su/
Examiner, Art Unit 3761
/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761